UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY
INSTITUTIONAL REVIEW BOARD APPLICATION

IRB USE ONLY
IRB #

DATE OF SUBMISSION:

_____

Type of Review Requested

☐ Full ☐ Expedited #___ ☐ Exempt #____

Start Date of Study
End Date of Study

TYPE OF RESEARCH (check all that apply)

☐ Laboratory ☐ Epidemiology

☐ Social ☐ Public Health

☐ Behavioral ☐ Clinical Trial

☐ Student ☐ Other (Specify) _____

Funding Sponsor: Internal Funding ☐ Pending receipt of funding ☐

Name(s)

Grant or Sponsor Protocol #:
Protocol Title: (must match full grant application/clinical trial title)

Principal Investigator Name and Contact Information		
Name:		Title:
Department/Institution		Complete Address:
Telephone:	Fax:	Email:
Department Chair:		If PI is a student, Faculty Advisor:

CO-INVESTIGATORS: NAME AND AFFILIATION

STUDY COORDINATORS AND SUPPORT PERSONNEL: NAME AND AFFILIATION

Age range of subjects: Lowest age		Highest age		Number of subjects to be enrolled at this site by this PI	

CATEGORIES OF HUMAN SUBJECTS

	Yes	No		Yes	No		Yes	No
Minors / children *(*Attach Appendix A-)*	* ☐	* ☐	Pregnant females	☐	☐	Psychiatrically impaired	☐	☐
Non-English speaking	☐	☐	Fetuses *(**Attach Appendix E)*	☐	☐	Cognitively impaired	☐	☐
Minorities	☐	** ☐	Abortuses *(**attach Appendix E)*	☐	☐	Prisoners (Note: must have prison approval)	☐	☐
Females	☐	☐	Healthy volunteers	☐	☐	Other	☐	☐
Genetic Materials	☐	☐	Students/Employees	☐	☐			

RESEARCH SITES SUMMARY

Multicenter Study? ☐ Yes ☐ No

Subjects at all centers:

Inter-institutional study with:
(Check one or more)

Newark	☐ Yes	☐ No	International Study?	☐ Yes ☐ No
New Brunswick	☐ Yes	☐ No		
Stratford/Kennedy (not yet available)	☐ Yes	☐ No		
Rutgers/UMDNJ 3T facility agreement	☐ Yes	☐ No		

Cooperative Agreement ☐ Yes ☐ No

RESEARCH SITES AND COOPERATIVE INSTITUTIONS (Names and Address):

CONFLICT OF INTEREST STATEMENT:

Do any of the investigators have a direct or indirect personal financial interest or advisory relationship to the sponsor, manufacturer, or to the owner of the test article? ☐ Yes ☐ No

If Yes, please explain:

If Yes, Have you filed a Financial Disclosure with the Research and Sponsored Programs Office ☐ Yes ☐ No
(Provide a copy of disclosure)

It is the responsibility of the IRB to assess the likelihood that a researcher's judgment may be influenced, or appear to be influenced, by private or personal interests, and assess the seriousness of any harm that is likely to result from such influence or from the mere appearance of undue influence. Competing interests may arise from family relationships, financial partnerships, advisory relationships with the sponsor, manufacturer, or to the owner of the test article or other economic interests. If you feel that you or any other member of the research team performing this study may have a conflict of interest, please explain.

Is there a Clinical Trial Agreement or Letter of Indemnification? ☐ Yes ☐ No

If Yes, attach clinical trial agreement or Letter of indemnification and budget:

COLLABORATING INSTITUTIONS

The proposed research will be carried out in cooperation with the following institution(s): (A copy of their IRB approval(s) is attached OR must be provided prior to IRB approval).

Investigator(s) Institution or Practice Address and Telephone Number

_____

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_____

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_____

_____

CHECK THE ITEMS BELOW THAT APPLY TO YOUR PROPOSED PROJECT:

- ☐ COST OF SUBJECTS
- ☐ FEES PAID TO SUBJECTS
- ☐ ADVERTISEMENT *(Attach)*
- ☐ UMDNJ LOGICIAN C-TRIAL REFERRAL SERVICE FOR ADVERTISEMENT AND STUDY RECRUITMENT
- ☐ MEDICAL COVERAGE NEEDED
- ☐ APPROVED DRUG FOR "UNAPPROVED USE"
- ☐ ADMINISTRATION OF INVESTIGATIONAL DRUG
- ☐ IND #_____ *(Provide a copy of FDA Form 1572)*
- ☐ USE OF AN INVESTIGATIONAL DEVICE
- ☐ IDE#_____ *(Provide a copy of FDA Form)*
- ☐ USE OF NONSIGNIFICANT RISK DEVICE
- ☐ USE OF SIGNIFICANT RISK DEVICE
- ☐ IRB FEE BUDGETED
- ☐ ADMINISTRATION OF CHEMICAL OR BIOLOGICAL AGENT
- ☐ PHASE I CLINICAL TRIAL
- ☐ PHASE II CLINICAL TRIAL
- ☐ PHASE III CLINICAL TRIAL
- ☐ PHASE IV POST MARKETING TRIAL
- ☐ FUTURE USE OF DATA, BLOOD PRODUCTS, BODY FLUID, OR TISSUE, DNA *(Include future use within consent form)*
- ☐ GENETIC MATERIAL/GENE THERAPY
- ☐ CREATE DATABASE OR REPOSITORY
- ☐ ELECTRICAL MEASURES
- ☐ USE OF IONIZING RADIATION
- ☐ SUBMITTED TO RADIATION SAFETY COMMITTEE
- ☐ USE OF MRI (1.5T; 2.0T, 2.5T, 3.0T, 4T)
- ☐ SUBMITTED TO BIOHAZARD/RNA COMMITTEE *(provide copy of review and approval)*
- ☐ HIV SCREENING
- ☐ TRANSLATED CONSENT FOR NON-ENGLISH SPEAKING SUBJECTS
- ☐ PHOTOGRAPHY
- ☐ VIDEO OR AUDIO TAPING
- ☐ DECEPTION AS PART OF THE PROTOCOL
- ☐ SURGERY
- ☐ ENDOSCOPY/ COLONOSCOPY
- ☐ LUMBAR PUNCTURE
- ☐ PAINFUL PROCEDURES
- ☐ ELECTRICAL SHOCK
- ☐ USE OF BLOOD, BLOOD PRODUCTS, BODY FLUID, OR TISSUE
- ☐ VENIPUNCTURE/ARTERIAL PUNCTURE
- ☐ CHART REVIEW & MEDICAL RECORDS
- ☐ PERSONAL HISTORY TAKING
- ☐ PSYCHOLOGICAL TESTS OR INVENTORIES *(Attach)*
- ☐ PSYCHOLOGICAL STRESS
- ☐ QUESTIONNAIRES *(Must attach)*
- ☐ OTHER *(Explain)*

Collaborative IRB Training Initiative (CITI) Course

Date Principal Investigator successfully completed CITI course_____ (Provide a copy of the completion certification for all investigators and support personnel)

For UMDNJ employees ONLY

Date Principal Investigator successfully completed RITE course_____ (Provide a copy of the completion certification for all investigators and support personnel)

Have all the personnel listed completed a profile on the University SMARTS/Genius system? Yes No

As part of a University-wide research administration project all applicants to the UMDNJ Campus IRB's must register on this system at **http://grants.umdnj.edu**. Your research office may have created a profile for you. Consult your local research office for further information and assistance.

BACKGROUND AND PURPOSE OF STUDY: (Provide 3 references)

SUMMARY OF PROPOSED PROJECT IN LAY TERMS(<500 words):
(attach a full protocol/grant and investigator's brochure)

- Why is the research being done?
- What procedures and/or processes will be used?

SUMMARY OF PROPOSED PROJECT IN SCIENTIFIC TERMS:

Outline of Proposed Study (Multi-center Clinical Trial - How will you implement this study at your site?)
(Include inclusion and exclusion criteria)

How will the study be analyzed?

WHAT ARE THE POTENTIAL BENEFITS TO SUBJECTS OR OTHERS?

WHAT ARE THE ACTUAL AND POTENTIAL RISKS TO SUBJECTS AND INCIDENCE (explain what the risks are and provide safety information (i.e. Package insert; investigators drug brochure)? (Must provide site monitoring correspondence and deviation reports after each visit)

- Is there a DSMB or DMC for this trial? Yes ☐No
  (If Yes, the PI must provide IRB with reports)

  If Yes, how frequently do they meet? _____

  What is the clinical trial registration # _____

WHAT ARE THE ALTERNATIVE TREATMENTS?

HOW WILL THE SUBJECT'S PRIVACY AND CONFIDENTIALITY BE PROTECTED?

RECRUITMENT PROCESS:

If you answer Yes to any one of the following, please provide additional details:

1. Are you going to recruit your own patients for this study? Yes ☐ No ☐

   If Yes, Outline the process for recruitment below:

Federal Guidelines state:

a. Ensure that women, members of minorities and their subpopulations are included in all human subject research.

b. For Phase III clinical trials, ensure that women, minorities and their subpopulations must be included such that valid analyses of differences in intervention effect can be accomplished;

c. Not allow cost as an acceptable reason for excluding these groups; and, initiate programs and support for outreach efforts to recruit these groups in clinical studies.

2. If non-English speaking subjects will be recruited has the consent form been translated into the appropriate language (provide copy of consent)?

   Yes ☐ No ☐

   If No, provide rationale.

3. Are you excluding children from this study.

   Yes ☐ No ☐
   (Attach Appendix A):

   If Yes, provide rationale.

4. Are you excluding females and minorities from this study.

   Yes ☐ No ☐

   If Yes, provide rationale.

5. Are you going to identify potential subjects from hospital or clinic records, logbooks, or schedules or any other institutional database?

   Yes ☐ No ☐
   (Explain)

RECRUITMENT PROCESS: (continued)

6. Are you going to identify potential subjects from a data/tissue repository or disease database?

   Yes ☐ No ☐
   (Explain)

7. Are you going to use commercial advertisement (including the Internet and e-mail) to recruit subjects? ***NOTE: All advertisements, flyers, brochures, web material, etc., must be attached and receive IRB approval prior to use.***

   Yes ☐ No ☐

8. Are you, the Sponsor or Contract Research Organization going to offer "finder's fees" for the referral of potential subjects?

   Yes ☐ No ☐

   If Yes, state the $ amount and the terms of the financial arrangement:

9. Does the study's Sponsor or Contract Research Organization offer financial incentives or bonuses to anyone involved in the study for recruitment of subjects (i.e., for expeditiously enrolling subjects)?

   Yes ☐ No ☐

   If Yes, how much is the incentive and what are the arrangements?

10. Are you going to use the services of a commercial company to identify and recruit potential subjects?

    Yes ☐ No ☐

    If Yes, explain the process:

PROCESS FOR OBTAINING CONSENT **(***Outline the process that will be used for obtaining consent/assent of your study participant. (ASSENT IS REQUIRED FOR UNDERAGED PARTICIPANTS, ages 7 - 17). (SEE Appendix B - Elements of Research Consent)*

1. Within the consent process, at what time points during the study will subjects be asked if they have questions?

2. Will they receive a copy of the written consent? ☐ Yes ☐ No
If no, explain why not:

3. How will the consent process be documented?

4. Where will the signed consent forms be kept?

(Campus, Building and Room #)

5. How will the subject's capacity to give consent be determined? (i.e., English is not first language; mental illness, disease affecting cognitive ability?)

6. Who Will Obtain Consent — Role in the Study

STEPS FOR OBTAINING AN ALTERATION/WAIVER OF CONSENT (*Explain your rationale) (See Appendix C) (Note: NJ State Law requires consent for prospective research)*

EDUCATIONAL PURPOSES OF PROPOSED STUDY:

Describe what educational activities, if any, will be furthered by the study, (e.g., participation of students, housestaff, postdoctoral fellows) and Involvement of University personnel in the proposed study: State all categories of UMDNJ employees who will contribute to the study.

PROVISION OF PATIENT CARE IN PROPOSED STUDY:

Describe what routine patient care versus medical care required by the research will be provided in the study.

PLANS FOR DISSEMINATING RESULTS OF PROPOSED STUDY:

State how results will be made available to the scientific community and/or the public.

ESTABLISHMENT OF DATA & SAFETY MONITORING BOARDS (DSMB)

The NIH requires the establishment of safety monitoring boards (DSMB) for all multi-site clinical trials involving interventions that entail risk to the participants. A plan for monitoring must be developed and approved by the IRB. Contact your campus IRB for the federal policy. FDA guidance advised that a Data Monitoring Committee (DMC) be formed for clinical trials.

INVESTIGATOR ASSURANCE

- *I AGREE TO ACCEPT RESPONSIBILITY FOR THE SCIENTIFIC CONDUCT OF THE PROTOCOL AND TO COMPLY WITH FEDERAL, STATE, UMDNJ and DHSS POLICIES RELATIVE TO THE PROTECTION OF THE RIGHTS AND WELFARE OF HUMAN SUBJECTS.*
- *I WILL SUBMIT TO THE IRB FOR REVIEW ANY CHANGES IN THE PROTOCOL PRIOR TO THEIR IMPLEMENTATION.*
- *I ALSO AGREE TO PROVIDE THE REQUIRED FINAL PROGRESS REPORT AT THE END OF THE STUDY AND/OR PROGRESS REPORT FOR CONTINUING REVIEW IN TIME TO HAVE THIS STUDY APPROVED BEFORE THE EXPIRATION DATE AS DIRECTED BY THE IRB.*
- *IF THIS APPLICATION IS APPROVED. I WILL ALSO REPORT ANY SERIOUS OR UNANTICIPATED ADVERSE EVENTS, INCLUDING DEATH, THAT OCCUR WITH MY SUBJECTS TO THE IRB WITHIN 24 HOURS AND WILL FORWARD AE REPORTS FROM THE COMPANY TO THE IRB WITHIN TWO WEEKS.*
- *I WILL ALSO PROMPTLY INFORM THE IRB OF ANY AND ALL PROTOCOL DEVIATIONS.*

Signature of Principal Investigator DATE

Signature of Co-Investigator DATE

Signature of Co-Investigator DATE

Signature of Co-Investigator DATE

Signature of Co-Investigator DATE

Signature of Co-Investigator DATE

Signature of Co-Investigator DATE

I HAVE REVIEWED THIS PROTOCOL AND APPROVE ITS' SUBMISSION TO THE IRB. THE INVESTIGATOR IS CREDENTIALED, HAS APPROPRIATE TRAINING TO CONDUCT THE RESEARCH AND HAS ADEQUATE RESOURCES AND STAFF TO PERFORM THE PROCEDURES OUTLINED IN THIS STUDY.

PRINCIPAL INVESTIGATOR'S SUPERVISOR OR DEPARTMENT CHAIR

_____	_____
NAME	TITLE
_____	_____
SIGNATURE	DATE